HFI-35 M931N

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1124788

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4099

May 22, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Geoffrey Sweet, President
NMC Homecare
Fresenius Medical Care
North America
2 Ledgemont Center
95 Hayden Avenue
Lexington, Massachusetts 02173

Dear Mr. Sweet:

During a Food and Drug Administration (FDA) inspection of your firm located in Columbia, Maryland on May 5, 6, and 8, 1997, our investigators documented deviations from current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211) during the oxygen manufacturing operation. These deviations cause your firm's Oxygen, U.S.P. to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (Act).

Deviations documented during the inspection include:

1. Failure to adequately calibrate the [redacted] Oxygen Analyzer according to the manufacturer's directions, in that your firm did not use the calibration gases specified. Your firm used a compressed gas with an unknown U.S.P. assay value, and failed to have a reference standard gas cylinder.

2. Failure to establish adequate written test procedures, in that Statement No. 6414, dated 1/22/96, entitled "Oxygen Analyzer Calibration" states, in part: "It is not necessary to perform calibration tests using certified pure tanks of oxygen when calibrating hand-held, fuel cell analyzers."

3. Failure to test each lot of bulk oxygen to determine conformance with appropriate specifications and strength. Your firm failed to analyze medical oxygen using full U.S.P. testing when you did not have a valid COA or a valid letter on file. A letter on file to replace the COA after November 1996 was incomplete, as the testing procedure was not stated.

4. Failure to assure that each person engaged in the transfilling of compressed medical oxygen has the education, training, or experience to enable that person to perform the assigned function. For example, employee training for transfilling Oxygen, U.S.P was not documented. Certificates on file for employees were incomplete, in that the supplier did not specify the type of analyzer in which the employees received training. Your firm fails to have documentation to show that employees have been trained in Good Manufacturing Practices.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

Federal agencies are advised of the issuance of all Warning Letters, so they may take this information into account when considering the award of contracts. By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. You should also include an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to the Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, Attention Jennifer Thomas, Compliance Officer.

Sincerely yours,

Peter M. Dubinsky
Acting Director
Baltimore District

cc: Mr. A. Herbert Holmes
General Manager
NMC Homecare
6935 G Oakland Mills Road
Columbia, Maryland 21045

bcc: HFI-35 (purged) ✓
HFR-MA200
HFR-MA250
HFR-MA295
HFR-MA240 (Patty)
HFA-224
HFC-210
HFD-320
HFD-322
EI File
Legal File

Mr. Dennis Carrol
Associate Regional Administrator
HCFA
Room 3100
3535 Market Street
Philadelphia, PA 19101 (purged)

David Denoyer
Maryland State Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215 (purged)

HFR-NE 240

97 BLT-37